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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent Application of Éric DUPONT, *et al.*	: Anticipated Group Art Unit: 1651 :
		: Examiner: Not Yet Assigned
Conf. No.:	Not Yet Assigned	:
		: Anticipated Class and Subclass:
Appln. No.:	Not Yet Assigned	: Class: 424
		: Subclass: 548
Filed:	Herewith	:
		:
For:	ANTI-TUMOR THERAPIES COMPRISING A COMBINATION OF A CARTILAGE EXTRACT AND AN ANTI-NEOPLASTIC AGENT PROVIDING HIGH EFFICACY AND LOW TOXIC SIDE EFFECTS	: Attorney Docket : No. **014985-6U1** : : :

PRELIMINARY AMENDMENT

Prior to the examination and calculation of fees in the above-identified patent application, please amend the application as follows:

In the claims:

Please cancel claims 1-15, without prejudice.

Please add new claims 16-33 as follows:

16. (New) An anti-tumor composition comprising

an anti-tumor amount of anti-neoplastic agent;

a side effect-reducing amount of a shark cartilage extract; and

a pharmaceutically acceptable carrier.

17. (New) The anti-tumor composition of claim 1, wherein the anti-neoplastic agent is selected from the group consisting of busulfan, thiotepa, chlorambucil, cyclophosphamide, estramustine sodium phosphate, ifosfamide, mechlorethamine hydrochloride, melphalan, carmustine, lomustine, streptozocin, carboplatin, cisplatin, methotrexate sodium, cladribine,

mercaptopurine, thioguanine, cytarabine, fluorouracil, hydroxyurea, daunorubicin, doxorubicin hydrochloride, epirubicin hydrochloride, idarubicin hydrochloride, dactinomycin, bleomycin sulfate, mitomycin, mitotane, mitoxantrone hydrochloride, etoposide, teniposide, docetaxel, paclitaxel, vinblastine sulfate, vincristine sulfate, vindesine sulfate, vinorelbine tartrate, altretamine, amsacrine, l-asparaginase, dacarbazine, fludarabine phosphate, porfimer sodium, procarbazine hydrochloride, tretinoin (all-trans retinoic acid), marimastat, suramin, TNP 470, thalidomide and radiotherapy.

18. (New) The anti-tumor composition of claim 16, wherein the anti-neoplastic agent is cisplatin.

19. (New) The anti-tumor composition of claim 16, wherein the shark cartilage extract comprises water-soluble molecules and a major portion of the water-soluble molecules have a molecular weight of less than about 500 kDa.

20. (New) The anti-tumor composition of claim 19, wherein the shark cartilage extract has been prepared by fractionating a crude shark cartilage extract comprising water-soluble molecules obtained from shark cartilage material such that a major portion of the molecules having a molecular weight of greater than about 500 kDa is separated from a major portion of the molecules having a molecular weight of less than about 500 kDa.

21. (New) The anti-tumor composition of claim 16, further comprising hypoxanthine.

22. (New) An anti-tumor composition comprising

a sub-optimal dosage amount of an anti-neoplastic agent;

a side effect-reducing amount of a shark cartilage extract; and

a pharmaceutically acceptable carrier that is an aqueous solution,

wherein administration of the anti-tumor composition causes less side effects than administration of a similar composition that does not contain shark cartilage extract.

23. (New) An anti-tumor composition comprising

an optimal dosage amount of an anti-neoplastic agent;

a side effect-reducing amount of a shark cartilage extract; and

a pharmaceutically acceptable carrier that is an aqueous solution,

wherein administration of the anti-tumor composition causes less side effects than administration of a similar composition that does not contain shark cartilage extract.

24. (New) An anti-tumor treatment kit comprising

a first composition comprising an anti-neoplastic agent; and

a second composition comprising a side effect-reducing amount of a shark cartilage extract.

25. (New) The anti-tumor treatment kit of claim 24, wherein the first composition and the second composition are each independently contained within a dosage form.

26. (New) The anti-tumor treatment kit of claim 24, wherein the anti-neoplastic agent is selected from the group consisting of busulfan, thiotepa, chlorambucil, cyclophosphamide, estramustine sodium phosphate, ifosfamide, mechlorethamine hydrochloride, melphalan, carmustine, lomustine, streptozocin, carboplatin, cisplatin, methotrexate sodium, cladribine, mercaptopurine, thioguanine, cytarabine, fluorouracil, hydroxyurea, daunorubicin, doxorubicin hydrochloride, epirubicin hydrochloride, idarubicin hydrochloride, dactinomycin, bleomycin sulfate, mitomycin, mitotane, mitoxantrone hydrochloride, etoposide, teniposide, docetaxel, paclitaxel, vinblastine sulfate, vincristine sulfate, vindesine sulfate, vinorelbine tartrate, altretamine, amsacrine, l-asparaginase, dacarbazine, fludarabine phosphate, porfimer sodium, procarbazine hydrochloride, tretinoin (all-trans retinoic acid), marimastat, suramin, TNP 470, thalidomide and radiotherapy.

27. (New) The anti-tumor treatment kit of claim 24, wherein the anti-neoplastic agent is cisplatin.

28. (New) The anti-tumor treatment kit of claim 24 wherein the shark cartilage extract comprises water-soluble molecules, a major portion of which have a molecular weight of less than about 500 kDa.

29. (New) The anti-tumor treatment kit of claim 24, wherein the shark cartilage extract has been prepared by fractionating a crude shark cartilage extract comprising water soluble molecules obtained from shark cartilage material such that a major portion of the molecules having a molecular weight of greater than about 500 kDa is separated from a major portion of the molecules having a molecular weight of less than about 500 kDa.

30. (New) The anti-tumor treatment kit of claim 24, wherein the anti-neoplastic agent is present in a sub-optimal dosage amount and at least one of the first and second compositions further comprises a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier is an aqueous solution, and administration of the compositions of the anti-tumor treatment kit causes less side effects than the administration of the compositions of a similar treatment kit that does not contain a composition containing shark cartilage extract.

31. (New) The anti-tumor treatment kit of claim 24, wherein at least one of the first and second compositions further comprises a pharmaceutically acceptable carrier, wherein said pharmaceutically acceptable carrier is an aqueous solution, the anti-neoplastic agent is present in an optimal dosage amount, and administration of the compositions of the anti-tumor treatment kit causes less side effects than the administration of the compositions of a similar treatment kit that does not contain shark cartilage extract.

32. (New) The anti-tumor treatment kit of claim 24, wherein the anti-neoplastic agent is cisplatin.

33. (New) The anti-tumor treatment kit of claim 17, wherein the first composition is contained within a parenteral dosage form and the second composition is contained within an oral dosage form.

REMARKS

Claims 16-33 are pending in the application. No new matter is incorporated by claims 16-33. Support for claims 16-33 is found at least in claims 11-15 as originally filed. New claims 16-33 contain non-elected subject matter (Group I, drawn to a method of reducing the severity of side effects of anti-neoplastic agents) restricted from U.S. Appln, No. 09/373,037 by the Examiner's restriction requirement, mailed March 27, 2001.

CONCLUSION

The applicants request examination and allowance of claims 16-33 at the earliest opportunity.

Respectfully submitted,

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(Date)

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